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IN THE  
**Supreme Court of the United States**

OCTOBER TERM, 1984

BRISTOL-MYERS COMPANY,

*Petitioner,*

—v.—

FEDERAL TRADE COMMISSION,

*Respondent.*

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES  
COURT OF APPEALS FOR THE SECOND CIRCUIT

**REPLY BRIEF OF PETITIONER  
BRISTOL-MYERS COMPANY**

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## TABLE OF CONTENTS

	PAGE
TABLE OF AUTHORITIES.....	ii
I. THIS COURT SHOULD RESOLVE THE CON- FLICT IN THE CASES GOVERNING THE PROPER STANDARD OF APPELLATE RE- VIEW OF FIRST AMENDMENT ISSUES .....	1
II. THE PRIOR SUBSTANTIATION DOCTRINE IS UNCONSTITUTIONAL BECAUSE IT IS BASED UPON AN UNSUPPORTED PRE- SUMPTION OF DECEPTION.....	2
III. DUE PROCESS REQUIRES ADEQUATE PRIOR NOTICE OF PROPOSED REMEDIES ..	4
CONCLUSION.....	6

## TABLE OF AUTHORITIES

Cases	PAGE
<i>Central Hudson Gas &amp; Electric Corp. v. Public Service Commission</i> , 447 U.S. 557 (1980) .....	4
<i>FTC v. National Lead Co.</i> , 352 U.S. 419 (1957).....	5
<i>Hormel v. Helvering</i> , 312 U.S. 552 (1941) .....	2
<i>McGoldrick v. Compagnie Generale Transatlantique</i> , 309 U.S. 430 (1940) .....	2
<i>Regents of the University of California v. Bakke</i> , 438 U.S. 265 (1978) .....	2
<i>Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.</i> , 425 U.S. 748 (1976) .....	3
<b>Constitutional Provisions</b>	
United States Constitution, First Amendment.....	<i>passim</i>
United States Constitution, Fifth Amendment .....	<i>passim</i>

IN THE  
**Supreme Court of the United States**  
OCTOBER TERM, 1984  
No. 84-650

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BRISTOL-MYERS COMPANY,

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—v.—

FEDERAL TRADE COMMISSION,

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ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES  
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**REPLY BRIEF OF PETITIONER  
BRISTOL-MYERS COMPANY**

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Petitioner Bristol-Myers Company respectfully submits this Reply Brief in response to the "Brief For the Federal Trade Commission in Opposition" ("FTC Brief") dated December, 1984.

**I. THIS COURT SHOULD RESOLVE THE CONFLICT  
IN THE CASES GOVERNING THE PROPER STAND-  
DARD OF APPELLATE REVIEW OF FIRST AMEND-  
MENT ISSUES**

The FTC concedes that there is a "standard of independent appellate review . . . for non-commercial speech cases . . . ." (FTC Brief at 6), but argues that this standard has never been applied to Commission findings of deceptive advertising. *Id.* Bristol-Myers submits that this inconsistency in the standards

of review applied to different forms of speech raises "an important question of federal law which has not been, but should be, settled by this Court . . . ." Rule 17.1.(c), Supreme Court Rules. *See also* FTC Brief at 6 (Bristol-Myers's contention has "potentially far reaching consequences").

Although this precise issue was not raised below (FTC Brief at 4-5), this Court's inclination to avoid considering issues not addressed by the Court of Appeals is, of course, not inflexible but subject to exception. *See Hormel v. Helvering*, 312 U.S. 552, 557 (1941). The reasons pressed by the FTC for deferring consideration of this important issue are not applicable here. In *McGoldrick v. Compagnie Generale Transatlantique*, 309 U.S. 430 (1940) (FTC Brief at 5), the petitioner sought for the first time to challenge the constitutionality of a state statute. The Court noted that in cases originating in state courts in which "a state statute is assailed as unconstitutional, there are reasons of peculiar force which should lead us to refrain from deciding questions not presented or decided in the highest court of the state whose judicial action we are called upon to review." 309 U.S. at 434. Similarly, in *Regents of the University of California v. Bakke*, 438 U.S. 265 (1978) (FTC Brief at 5), the Court was "hesitant" to review arguments not raised in the state court below, relying upon *McGoldrick*. The principles of comity involved in those two cases are not applicable here.

Accordingly, this Court should reevaluate the substantial evidence standard of review in light of the conflicting principles of appellate review in recent First Amendment cases.

## **II. THE PRIOR SUBSTANTIATION DOCTRINE IS UNCONSTITUTIONAL BECAUSE IT IS BASED UPON AN UNSUPPORTED PRESUMPTION OF DECEPTION**

Contrary to the FTC's characterization of Bristol-Myers's position (FTC Brief at 8), Bristol-Myers does not contend that unsubstantiated advertising claims are never deceptive. The thrust of Bristol-Myers's challenge is that under the prior substantiation doctrine the FTC does not consider how con-

sumers interpret the advertisement at issue to determine whether the advertisement is in fact deceptive. Instead, the FTC prohibits commercial speech on the basis of its unsupported assumption that all advertisements that are not substantiated by a particular level or type of support are deceptive as a matter of law.

Indeed, even in this Court the FTC states that “consumers expect objective advertising claims to be appropriately supported . . . .” (FTC Brief at 8) without citing any evidence to support this contention. Bristol-Myers submits that, under this Court’s decision in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976), prior to entering a cease and desist order, the FTC should be required to find in each case that the challenged advertisements are deceptive, and not to rely upon broad and far-reaching assumptions.

The constitutionality of the prior substantiation doctrine is squarely raised in this case. Contrary to the FTC’s assertions (FTC Brief at 9), it is readily apparent, with respect to the advertisements which form the basis of Part II of the Order, that the FTC relied upon the prior substantiation doctrine’s presumption and did not find that these advertisements were in fact deceptive. None of the pages of the final Opinion cited by the FTC (FTC Brief at 9 n.12) contains a finding that these advertisements were deceptive.\*

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\* The advertising claim discussed at Opinion 84a was a hypothetical claim raised by the FTC for purposes of discussion only, and was not a claim involved in this case. At Opinion 81a n.65, the FTC merely reiterated its rule, which Bristol-Myers is challenging in this Court, that all advertisements lacking a “reasonable basis” are deceptive. At Opinion 82a-84a, the FTC stated in general terms that because it has no evidence of consumer expectations, it requires advertisements to be supported by a reasonable basis rather than by a specific level of scientific proof. Finally, Opinion 117a-118a contains a discussion of the reasons why the FTC entered a specific type of reasonable basis provision in this case.

Addressing the merits, the FTC argues that it may curtail commercial speech that is not deceptive if such speech “potentially lends itself to falsity and deceit.” FTC Brief at 9 n.14. Nevertheless, it is well-established that non-deceptive speech may be restrained only if the restraint imposed is the least restrictive alternative available to advance a substantial governmental interest. *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 566 (1980). Bristol-Myers contends that the least restrictive alternative available to the FTC would be to determine on a case-by-case basis whether the advertisements at issue are deceptive, and not to rely upon assumptions. The Court should grant certiorari to address these issues.

### **III. DUE PROCESS REQUIRES ADEQUATE PRIOR NOTICE OF PROPOSED REMEDIES**

In response to Bristol-Myers’s contention that its due process right to fair notice was violated in connection with Part III-A of the Final Order, the FTC argues that Bristol-Myers had adequate notice of the aspirin non-disclosure violation, cited by the FTC as justifying Part III-A. FTC Brief at 11-12. The FTC, however, does not deny that, prior to the entry of the Final Order by the Commission, the parties had always related Part III-A to the special ingredient allegations of the Complaint and that Bristol-Myers had no notice whatsoever that Part III-A might be entered as a remedy for the alleged aspirin non-disclosure violation. The FTC thus takes the extraordinary position that it may enter any remedial order that is “reasonably related” to a substantive violation without providing any prior notice to the advertiser of the nature of the proposed order or the basis for its entry.

As Bristol-Myers emphasized in its Petition (at p. 12), it has never challenged the FTC’s jurisdiction to fence-in an advertiser with “reasonably related” remedial provisions somewhat broader than the specific substantive violation. Instead, Bristol-Myers submits that the entry of an order, even one that may

prove to be "reasonably related" to the violation, without adequate prior notice of the nature and scope of the proposed relief, deprives the advertiser of the opportunity to defend on these critical issues, and is therefore a violation of administrative due process.

The cases cited in the FTC Brief at 11-12 are inapposite. None holds, as the FTC suggests, that the FTC may issue a remedial order without providing the respondent with due notice of the basis for its entry. Moreover, in *FTC v. National Lead Co.*, 352 U.S. 419, 428-29 (1957), this Court emphasized the importance of prior notice in FTC proceedings. In the very same paragraph quoted by the FTC (FTC Brief at 11), the Court recognized that "[i]t goes without saying that the requirements of a fair hearing include notice of the claims of the opposing party and an opportunity to meet them." 352 U.S. at 427. This Court went on to find that, unlike in the present proceeding, "[t]he record indicates that the respondents were afforded those safeguards" and "the record is replete with evidence that counsel supporting the complaint would seek the use of such a [remedy]." *Id.*

Finally, the FTC asserts that Bristol-Myers's due process challenge against Part III-A of the Order was not raised in the court below. FTC Brief at 11 n.17. In fact, Bristol-Myers raised this precise argument below citing the same cases cited in the Petition filed in this Court, as is clearly documented in its Reply Brief and in its Petition For Rehearing in the Second Circuit. (The pages of Bristol-Myers's Reply Brief and Petition For Rehearing in the Second Circuit setting forth its challenge against Part III-A of the Order are reproduced at the end of this Brief, at pages 1a-5a.)

This Court, therefore, should grant certiorari to decide the important due process issue raised in the Petition.



### CONCLUSION

For the reasons expressed above and in the Petition, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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Dated: January 7, 1985

**Excerpt from Reply Brief of Petitioner Bristol-Myers Company, United States Court of Appeals For the Second Circuit, dated March 8, 1984, pages 16-18.**

**B. The Part IV Findings, Which Did Not Involve Any Special or Unusual Ingredient Claims, Do Not Support Part III-A**

The FTC maintains that Part III-A is supported by the findings underlying Part IV—that Bristol-Myers had represented that BUFFERIN and EXCEDRIN contain analgesic ingredients different from aspirin. FTC Brief 44-46. The FTC asserts that, in connection with Part IV, it had “found that Bristol-Myers had improperly utilized claims that its ingredients were ‘special’ or ‘unusual’ as a means of product differentiation.” FTC Brief 44, 46.

There was no such finding in the Opinion. In entering Part IV, the FTC found that Bristol-Myers had represented that BUFFERIN and EXCEDRIN contain an analgesic ingredient *different* from aspirin. *E.g.*, Opinion 50, 51 (A 474, 475) (advertisements “differentiate” or “distinguish” BUFFERIN’s analgesic ingredient from aspirin). The Opinion found that Bristol-Myers had done so by “several means,” such as “strained syntax” or referring to aspirin by some other name. Opinion 50 (A 474). The FTC, however, never found that any of these “several means” included the claim that the analgesic ingredient was “special” or “unusual.” *See* Opinion 49-52 (A 473-76).

By contrast, when the FTC has in fact meant to challenge a special ingredient claim, its intent has been clearly evidenced by its use of words such as “special” or “unusual.” For example, the Complaint alleged that Bristol-Myers had represented that EXCEDRIN P.M. contains a “special” sleep-inducing agent “available only in EXCEDRIN P.M.” (Complaint ¶ 23, A 15) and the ALJ found that “Bristol-Myers has represented that the mild sedative or sleep inducing agent contained in Excedrin P.M. is *special* and *unique* . . . .” Initial Decision 93 (emphasis added) (A 214).

Likewise, in the *Sterling* case, the complaint alleged, and the FTC found, that Sterling had falsely represented that its analgesic product COPE was “unique.” *Sterling* Complaint ¶ 22 (Binder Ex. 1); *Sterling* Opinion 49 (Binder Ex. 4). In *AHP*, the complaint alleged that AHP had represented that “Anacin’s analgesic ingredient is *unusual, special*, and stronger than aspirin . . . .” *AHP* Complaint ¶ 8.a.2, 98 F.T.C. at 141 (emphasis added). The FTC found that AHP’s advertisements had created the “impression that the products are based on some *special, unusually* strong pain reliever entirely different from and superior to aspirin.” 98 F.T.C. at 366 (emphasis added).

The FTC has not cited a single reference to the Complaint, trial, Initial Decision or papers on appeal to the Commission to dispute that, throughout the history of this case, Part III-A had always been based on the EXCEDRIN P.M. allegations pertaining to a sleep-inducing ingredient. If Part III-A is now premised upon a new theory (that Bristol-Myers had represented that its products contain a special or unusual *analgesic* ingredient), which had not been pleaded, it should be stricken on that ground alone. See *Jaffee & Co. v. SEC*, 446 F.2d 387, 393-94 (2d Cir. 1971) (order stricken because it was based on a theory of liability that was not adequately pleaded in the complaint); *Spiegel, Inc. v. FTC*, 540 F.2d 287, 296 (7th Cir. 1976) (“an order should follow the complaint; otherwise it is improvident and, when challenged, will be annulled by the court”). See also *SEC v. Chenery Corp.*, 318 U.S. 80, 94, 95 (1943).

For the foregoing reasons, Part III-A should be set aside. See *Litton Industries, Inc. v. FTC*, 676 F.2d 364, 372 (9th Cir. 1982) (all provisions in final order relating to “test” results stricken where FTC’s findings related only to “survey” results). Cf. *Fedders Corp. v. FTC*, 529 F.2d 1398, 1403 (2d Cir.), *cert. denied*, 429 U.S. 818 (1976) (order provision relating to certain performance claims upheld solely because the FTC had expressly found that the challenged advertisements had implicitly made these claims).

**Excerpt from Petition For Rehearing by Petitioner Bristol-Myers Company, United States Court of Appeals For the Second Circuit, dated July 9, 1984, pages 7-11.**

## **II.**

### **PART III-A VIOLATES BRISTOL-MYERS'S RIGHT TO DUE PROCESS**

In affirming Part III-A, relating to special and unusual ingredient claims for all over-the-counter drug products, this Court subscribed to the Commission's view that the provision serves as proper fencing-in of the violations underlying Part IV of the Order, relating to the non-disclosure of the aspirin content of two internal analgesic products. (Slip op. at 4750). Bristol-Myers, however, had no prior notice in the administrative proceeding that Part III-A might be entered against it as "fencing-in" of the aspirin non-disclosure violations. Accordingly, the entry of Part III-A violated Bristol-Myers's due process right to have fair notice of the issues to be resolved against it, and this Court should grant hearing because its opinion does not address the due process issue raised in the briefs. (Brief 32-33; Reply Brief 17-18)

In its brief in this Court, the FTC did not dispute that the special or unusual ingredient claims were first associated with aspirin non-disclosure in the passage quoted by this Court from the FTC's Final Opinion, issued ten years after this case was brought. (See Slip op. at 4750; Opinion at 73 (A. 497)). Prior to the FTC's opinion, all references to "special" or "unique" ingredients were made in connection with the allegation, ultimately dismissed by the FTC, that Bristol-Myers had purportedly represented falsely that EXCEDRIN P.M. contained a special or unusual ingredient. (See Brief at 31-32). The Commission, therefore, justified its entry of Part III-A on a basis never raised by the Complaint and never litigated by the parties.<sup>1</sup>

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<sup>1</sup> This Court stated, we submit incorrectly, that a provision similar to Part III-A was entered in AHP as "fencing-in". (Slip op. at 4750). In AHP,

This Court has in this and previous cases upheld the FTC's exercise of broad discretion to fence-in violators of the FTC Act. *E.g. Jay Norris, Inc. v. FTC*, 598 F.2d 1244, 1249, 1251 (2d Cir.), *cert. denied*, 444 U.S. 980 (1979). Because this discretion is so broad, prior notice of the nature of the remedy that may be imposed is obviously essential if the respondent is to have an opportunity to present a defense in the administrative proceedings.

The FTC certainly would not be prejudiced by application of the fair notice requirement to "fencing-in" provisions, since it routinely serves proposed orders with its complaints and its prehearing procedures require full disclosure of the contentions of both parties. On the other hand, the prejudice to the respondent of relieving the FTC of this requirement is very real, as illustrated in this case.

Had Bristol-Myers been aware that the Part III-A might be entered, not in connection with the EXCEDRIN P.M. allegations, but as fencing-in of the violations underlying Part IV, it would have had an opportunity to introduce evidence showing that such fencing-in was inappropriate or that the prohibited conduct was not "like and related" to the underlying violation. *See Jaffee & Co. v. SEC*, 446 F.2d 387, 394 (2d Cir. 1971) ("Had Jaffee & Co. been afforded adequate notice, it would have had an opportunity, both to take action to lessen the attractiveness of invoking derivative sanctions and to introduce evidence before the hearing examiner tending to show that the use of such sanctions would not have been in the public interest.").

Bristol-Myers did not receive such notice until the final order was entered and therefore it had no opportunity to develop or present such a defense. Indeed, the prejudice here was particu-

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the complaint had expressly alleged that AHP had represented that "Anacin's analgesic ingredient is unusual, special and stronger than aspirin" and the FTC specifically found that AHP had made that special ingredient claim. (See Brief at 17). In contrast to the present case, therefore, the order provision in AHP was not entered as fencing-in but rather to remedy a specific violation found by the FTC.

larly acute since the FTC had always associated proposed Part III-A with the EXCEDRIN P.M. special-ingredient allegations, thereby giving Bristol-Myers every reason to believe that the dismissal of these allegations would result in the dismissal of Part III-A, and not in its use as fencing-in of unrelated violations.

The impropriety of the FTC's entry of Part III-A is confirmed by this Court's opinion in *Jaffee & Co. v. SEC*, 446 F.2d 387 (2d Cir. 1971) (cited in Reply Brief at 17), in which this Court held that an administrative order violated due process because the respondent did not receive adequate notice of the grounds on which the order would be entered.<sup>2</sup> *Accord In re Ruffalo*, 390 U.S. 544, 552 (1968) (court reversed disbarment order because attorney had no notice that certain conduct would be considered a disbarment offense until after he testified, holding that "[t]his absence of fair notice as to the reach of the grievance procedure and the precise nature of the charges deprived petitioner of procedural due process."). See also *Spiegel, Inc. v. FTC*, 540 F.2d 287, 296 (7th Cir. 1976) ("[A]n order should follow the complaint; otherwise it is improvident and, when challenged, will be annulled by the court.'").

For the foregoing reasons, the Court should grant a rehearing and strike Part III-A on the ground that it violates Bristol-Myers's due process right to fair notice.

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2 Although the potential for fencing-in is a theoretical possibility in FTC proceedings, the argument that the mere potential for a broad order serves as sufficient notice to comport with due process was rejected by this Court in *Jaffee*. In *Jaffee* this Court recognized that "the potential for derivative sanctions was of course inherent in the facts of the case from the outset . . . ." Since the suggestion that the Commission would actually pursue such sanctions was not raised until the conclusion of the hearing, the imposition of the sanctions violated Jaffee's right to due process. 446 F.2d at 393.

## **CERTIFICATE OF SERVICE**

I, Kenneth A. Plevan, a member of the Bar of this Court and counsel for Petitioner herein, hereby certify that on this 7th day of January, 1985 the "Reply Brief of Petitioner Bristol-Myers Company" was served upon all parties required to be served by hand delivery of three copies of same to:

- 1) Office of the General Counsel  
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